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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,640	12/01/2004	Robert E Click	Paralab I	6993
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Bourget Law P.O. BOX 81 EAU CLAIRE, WI 54702-0081			EXAMINER MACAULEY, SHERIDAN R	
			ART UNIT	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/516,640	<b>Applicant(s)</b> CLICK, ROBERT E	
	<b>Examiner</b> SHERIDAN R. MACAULEY	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-29 and 31-44 is/are pending in the application.
- 4a) Of the above claim(s) 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26 and 32-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A response and amendment were received and entered on September 17, 2009. New claims 41-44 have been added. Claims 1-25 and 30 are cancelled. Claims 26-29 and 31-44 are pending. Claims 27-29 are withdrawn due to a previous requirement for restriction. Claims 26 and 31-44 are examined on the merits in this office action.

#### ***Claim Rejections - 35 USC § 112***

Rejections under 35 USC 112 have been withdrawn due to applicant's statements made in the declaration for deposit of biological material filed on September 17, 2009.

#### ***Claim Rejections - 35 USC § 101***

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 26 and 38-40 stand rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite a composition comprising a bacterium of the genus *Dietzia*, or some fragment thereof. Bacteria of the genus recited in the claims are found in nature, i.e. in natural compositions, as evidenced by Duckworth et al. (Extremophiles, 1998, 2:359-366; document cited in IDS), who teach a strain of *Dietzia* found in a natural soda lake. The claims do not recite the composition to be isolated or in some way separate from the natural environment.

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Therefore, the claims read on a product of nature and are thus directed to non-statutory subject matter.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 26 and 38-40 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nishimaki et al. (US 5,989,892), as evidenced by Rainey et al. (International Journal of Systematic Bacteriology, 1995, 45:32-36; document cited in IDS). The claims recite a composition comprising a pharmacologically active dose of a bacterium of the genus *Dietzia*, and active thereof or a protein secreted therefrom, such that the dose is capable of reducing or preventing symptoms of a disease or syndrome whose causative agent is a mycobacterium.

5. Nishimaki teaches compositions comprising bacteria of the species *Rhodococcus maris* (col. 8, lines 37-47). *Rhodococcus maris* was renamed *Dietzia maris*, as taught by Rainey (abstract). The reference teaches cultures of the bacterial strain, which would comprise a pharmacologically active dose. Therefore, the reference teaches compositions comprising bacteria of the genus *Dietzia*, which would perform the function recited in the claims.

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6. Note that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

7. Therefore, the reference anticipates the cited claims.

8. Claims 26 and 38-40 stand rejected under 35 U.S.C. 102(b) as being anticipated by Duckworth et al. (Extremophiles, 1998, 2:359-366; document cited in IDS). The claims recite a composition comprising a pharmacologically active dose of a bacterium of the genus *Dietzia*, and active thereof or a protein secreted therefrom, such that the dose is capable of reducing or preventing symptoms of a disease or syndrome whose causative agent is a mycobacterium.

9. Duckworth teaches a strain of *Dietzia* found in a natural soda lake and compositions comprising the isolated strain (abstract), which would perform the function recited in the claims. The reference teaches cultures of the bacterial strain, which would comprise a pharmacologically active dose.

10. Therefore, the reference anticipates the cited claims.

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious

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at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 26 and 32-40 stand rejected under 35 U.S.C. 103(a) as being

unpatentable over Alkemade et al. (US 6,139,844) in view of Mosser (WO 99/05304)

and Rainey et al. (International Journal of Systematic Bacteriology, 1995, 45:32-36;

document cited in IDS). The claims recite a composition comprising a pharmacologically

active dose of a bacterium of the genus *Dietzia*, and active thereof or a protein secreted

therefrom, such that the dose is capable of reducing or preventing symptoms of a

disease or syndrome whose causative agent is a mycobacterium. The claims further

recite that the composition comprises an animal feed comprising various components

and a feed additive, such as a vitamin, mineral, protein supplement or drug. The claims

further recite that the composition is incorporated into a dosage form such as a tablet

comprising various components.

14. Alkemade teaches the compositions comprising components of bacteria of the

Actinomycetales, such as *Rhodococcus* or *Nocardia*, for administration to animals (col.

2, lines 36-60). Alkemade teaches that such compositions may be prepared in various

formulations, such as a tablet that contains a base (e.g., powder), disintegrator (e.g.

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dispersing agent), absorbent, binder and lubricant (col. 6, line 54-col. 7, line 5). The reference teaches that the compositions may be formulated for oral administration, such as in a lozenge, which would comprise an edible product such as those recited in the claims and a mineral such as a salt (col. 7, lines 6-31). The reference does not specifically teach the use of a species of the genus *Dietzia*.

15. Mosser teaches the preparation of strains of *Rhodococcus* for use in eliciting an immune response that may be an active *Rhodococcus* cell or an immunogenic fragment thereof, such as a protein (abstract, p. 8, lines 4-14; p. 12, lines 10-21).

16. Rainey teaches that members of the genus *Dietzia* are closely related to *Rhodococcus* and were once considered to be in the same genus (p. 359).

17. At the time of the invention, bacteria of the Actinomycetales, such as *Rhodococcus*, were known to be useful in compositions for the administration to animals, as taught by Alkemade and Mosser. At the time of the invention, species of the genus *Dietzia* were known to be closely related to and previously considered to be of the same genus as *Rhodococcus*. Although none of the references specifically teach compositions comprising bacteria of the genus *Dietzia*, Alkemade and Mosser teach that one would have a reasonable expectation of success in selecting any species of *Rhodococcus* or related organisms for the preparation of compositions such as those recited in the claims. One would therefore have been able to choose from the finite number of identified, predictable species of bacteria for the preparation of such compositions, *Rhodococcus maris* (i.e. *Dietzia maris*) being one of them. One would therefore have been motivated to practice and would have had a reasonable

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expectation of success in practicing the claimed invention. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

18. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

### ***Response to Arguments***

19. Applicant's arguments filed September 17, 2009 have been fully considered but they are not persuasive. Applicant argues that the claims are patentable under 35 USC 101 because the Duckworth reference teaches an isolate from a natural environment and because the claims recite a pharmacologically active dose of the organism.

Applicant argues that the claims are patentable under 35 USC 102 because the cited references do not recite a pharmacologically active dose of the organism. Applicant argues that it would not have been obvious to one of ordinary skill in the art to combine the teachings discussed in the above rejections to arrive at the claimed invention because Rainey teaches away from the consideration of bacteria of the species *Dietzia* as species of the genus *Rhodococcus*. Applicant also argues that the claims are not rendered obvious because Alkemade and Mosser do not teach that any species of *Rhodococcus* may be used with a reasonable expectation of success in the preparation of compositions such as those recited in the claims, and that a finite number of predictable species from which a composition could have been prepared has not been identified.



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20. In response to applicant's argument that the claims are patentable under 35 USC 101, it is noted that, although the Duckworth reference teaches isolated organisms from the genus *Dietzia*, the reference also teaches that the organism is found in natural environments. Thus, samples of the natural environment (from which the isolates were obtained) comprised organisms of the genus. Therefore, such an environment is a composition comprising bacteria of the genus *Dietzia*. Although applicant also argues that the claims do not read upon a product of nature because the claims recite a pharmacologically active dose of the organism, it is noted that an organism that is present in a natural environment would be present in a number that would constitute an effective dose, even if such a dose is distributed across a large area. Therefore, a soda lake, as taught by Duckworth to contain organisms of the genus *Dietzia*, would read upon the composition of the claim. Applicant is advised that a claim reciting "a pharmacologically active dose of an isolated bacterium of the genus *Dietzia*" would not read upon a product of nature.

21. In response to applicant's argument that the claims are patentable under 35 USC 102 because the cited references do not recite a pharmacologically active dose of the organism, it is noted that the claims recite a composition and method in terms of a function, property or characteristic. Once rationale is provided to show that the claimed invention appears to be the same or similar to that of the prior art, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (MPEP 2112). Since the references cited in the rejections above teach cultures of the same strains recited in the claims, and

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cultures of these strains are known to possess the claimed characteristic, as discussed in applicant's disclosure, the prior art compositions would inherently possess the characteristic recited in the claims.

22. In response to applicant's argument that it would not have been obvious to one of ordinary skill in the art to combine the teachings discussed in the above rejections to arrive at the claimed invention because Rainey teaches away from the consideration of bacteria of the species *Dietzia* as species of the genus *Rhodococcus*, it is noted that the reference teaches that bacteria of the species *Dietzia* were once considered species of the genus *Rhodococcus*. Although the reference teaches that various analyses have caused the nomenclature of the organism to be revised, the bacteria were once considered to be of the same species based upon various biological characteristics. Although the organism is not as similar as it once had been considered, as discussed by Rainey, the revised nomenclature would not have precluded one of ordinary skill in the art from selecting *Dietzia maris* (formerly *Rhodococcus maris*) from organisms of the genus *Rhodococcus* for use in compositions comprising such organisms. Therefore, applicant's argument is not found to be persuasive.

23. Regarding applicant's argument that the claims are not rendered obvious because Alkemade and Mosser do not teach that any species of *Rhodococcus* may be used with a reasonable expectation of success in the preparation of compositions such as those recited in the claims, it is noted that Alkemade teaches that species of *Rhodocci* and *Norcardia* are useful in the compositions as nonspecific stimulators of the immune system (col. 2, lines 44-55) and that Mosser teaches the use of any avirulent

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strain of *Rhodococcus* (p. 8, lines 9-11); thus, one would have recognized that any species of the *Rhodococcus* genus could have been used in the compositions described in the references. Regarding applicant's argument that a finite number of predictable species from which a composition could have been prepared has not been identified, it is noted that species of the *Rhodococcus* and *Dietzia* genera have been identified in Rainey, who sets forth many species related to those taught to be useful in the references and those recited in the claims (see p. 32, col. 2-p. 33, col. 1), and therefore a finite number of predictable *Rhodococcus* and *Dietzia* that could have been selected from Rainey for use in the composition recited in the claims. Therefore, applicant's arguments have not been found to be persuasive.

24. Although applicant argues that a *prima facie* case of unpatentability was not made in the previous Office action, therefore precluding the finality of this action, it is noted that the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art, as set forth in the above rejections and responses to applicant's arguments. Therefore, the finality of this Office action is proper.

25. Thus, applicant's arguments have been fully considered, but they have not been found to be persuasive.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/

Primary Examiner, Art Unit 1651